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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,667	03/18/2004	Yasuhiro Sakai	3029-74DIV	6011
<div>7590 04/18/2007 Lance J. Lieberman, Esq. Cohen, Pontani, Lieberman & Pavane Suite 1210 551 Fifth Avenue New York, NY 10176</div>			<div>EXAMINER HA, JULIE</div> <div>ART UNIT PAPER NUMBER 1654</div>	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/803,667	Applicant(s) SAKAI ET AL.	
	Examiner Julie Ha	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election/Restriction filed on February 27, 2007 is acknowledged. Claims 1-19 are pending in this application.

Restriction

1. Applicant's election of sulfamic acid from claim 2, dye represented by compound formula 10 (with Dye A) from claim 3, tetradecyl trimethyl ammonium salt from claims 5 and 6, and citric acid-NaOH in the reply filed on February 27, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). A search was conducted on the elected species of compound formula 10 (Dye A), sulfamic acid as the nitrite ion reducing agent, tetradecyl trimethyl ammonium salt and citric acid-NaOH and this composition was found to be free of the prior art. Search was then extended to the Markush group (base claim) and prior art was found on the base claim. Claims 1-19 are examined on the merits in the office action.

Objection-Minor Informalities

2. The title is objected to because the title is too long. The title is limited to 2-7 words maximum. A new title is required that is clearly indicative of the invention to which the claims are directed.

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3. Claim 13 is objected to because there is an error. The word "can reduces" should be "can reduce". Applicant is requested to correct the error.

Rejection-35 U.S.C. 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Horan et al (US Patent # 4783401).
6. The instant claims are drawn to a method of staining bacteria comprising adding a polymethine dye to a sample in the presence of a substance capable of reducing nitrite ions (glycine) to stain bacteria in the sample.
7. Horan et al teach methods for reproducibly labeling viable cells with cyanine dyes that do not significantly affect cell viability (see abstract). The reference teaches that any viable cell can be labeled with cyanine dye...prokaryotic cells such as bacteria, nucleated eukaryotic cells, various tumor cells, and mammalian cells (see column 4, lines 10-14). As evidenced by Ernst et al (Cytometry, 1989, 10: 3-10), cyanine dyes are introduced as new fluorescent reagents for covalently labeling proteins and other biomolecules. And these cyanine dyes are polymethine dyes, since the reference teaches that a major advantage of these polymethine dyes is the easy manipulation of

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their spectral properties during synthesis (see abstract). Therefore, this reads on claim 1 in part. Furthermore, Horan et al teach that cell labeling is performed in a medium that is non-lethal to cells and that provides for reproducible cell labeling...osmolarity regulating agents in which cyanine dyes form stable solutions for at least as long as required for labeling as used...acceptable agents include...glycine (see column 4, lines 24-36).

Thus this reads on claims 1 in part and 2.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Inoue et al (EP 1136563 A2).

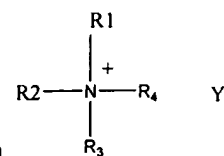
9. The instant claims are drawn to a method of staining bacteria comprising adding a polymethine dye to a sample in the presence of a substance capable of reducing nitrite ions to stain bacteria in the sample. The claims are further drawn to a method of staining bacteria wherein the substance capable of reducing nitrite ions is selected from the group consisting of: ...glycine..., wherein the polymethine dye is at least one selected from the following:formula 10..., in the presence of a cationic surfactant (quarternary ammonium salt), in an acidic state set at pH 2.0 to 4.5; wherein a buffer pKa is 1.0 to 5.5, and the buffer is at least one selected from the group consisting of: citric acid-NaOH...

10. Inoue et al disclose a method of staining bacteria comprising mixing a sample with an aqueous solution containing a cationic surfactant to accelerate dye transmissivity of bacterial at pH 2.0 to 4.5; and staining the bacteria for a predetermined

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period with a dye (see abstract, 1st sentence and claim 1). This reads on claims 4-6 and 18. The reference further discloses a method of detecting bacteria comprises the following steps of 1) mixing a sample with an aqueous solution containing a cationic surfactant and staining the bacteria with a dye, 2) introducing the thus treated sample into a detecting part of a flow cytometer and irradiating cells of the stained bacteria one by one with light to measure scattered light and fluorescent light emitted from each of the cells, and 3) discriminating the bacteria from other components in accordance with an intensity of a scattered light signal and an intensity of a fluorescent light signal or a pulse width reflecting the length of particles to count the bacteria (see abstract, 2nd sentence and claim 12). This meets the limitations of claim 17. Additionally, the reference discloses the types of polymethine dyes (see claim 3, paragraphs [0020] to [0024] and pp. 3-7). Please note that claim 3 of EP patent discloses all of the polymethine dyes disclosed in the instant application. This meets the limitation of claim 3. Additionally, the reference discloses that one of the suitable buffers is explicitly stated to be glycine (see paragraph [0026]). Thus, glycine may function as both the buffer recited (see instant application claim 10) in the claims and the nitrite reducing agent (see instant application claim 2). This reads on claim 2. Further, the reference discloses that the concentration of the dye is determined depending on the kind of dye, for example, in the range of 0.1 to 100 ppm (final concentration) (see paragraph [0020]). This meets the limitation of claim 12. Additionally, the reference discloses that in general, the presence of bacteria of 10^5 or more/ml in urine is recognized as a criterion of positive urinary tract infection (see paragraph [0002]). Therefore, this meets the

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limitation of claim 13. Further, the reference discloses the formula

wherein R_1 is a C_{8-18} alkyl group, R_2 , R_3 and R_4 , the same or different, are C_{1-3} alkyl group or benzyl group, Y^- is a halogen ion (see p. 3, paragraph [0016] and claim 4). This meets the limitation of claim 5. Paragraph [0018] discloses the examples of suitable quarternary ammonium salt, one of them listed is tetradecyl trimethyl ammonium salt (see p.3). This meets the limitation of claim 6. Please note, paragraph [0018] also discloses all of the quarternary ammonium salts disclosed in claim 6 of the instant application. The reference further discloses that appropriate uses amount of quarternary ammonium salts may be 10 to 30000 mg/l (see paragraph [0018] and claim 5). This meets the limitation of claim 14. Furthermore, the reference discloses that a buffer of pKa 1 to 5.5 is used to maintain the acidic state (see claim 6 and paragraph [0026]). Additionally, the reference discloses that as the buffer, it may be utilized one or more kinds of compounds...suitable examples thereof...citric acid-NaOH, potassium dihydrogen phosphate-disodium hydrogen phosphate, potassium dihydrogen phosphate-NaOH... (see paragraph [0026] and claim 7). This meets the limitation of claims 9-10. Please note, paragraph [0026] discloses all of the buffers disclosed in claim 10 of instant application. Furthermore, the reference discloses that the appropriate use amount thereof (acid) is such that the above-mentioned pH range is maintained, preferably about 10 to 500 mM in the sample (see last sentence of paragraph [0026] and claim 11). This meets the limitation of claim 15. The reference discloses that a method of staining bacteria is carried out in the existence with an inorganic salt or either

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sulfate or nitrate (see claim 8). This meets the limitation of claim 11. Additionally, the reference discloses a method wherein the step (3) of discriminating and counting the bacteria is carried out in accordance with at least one selected from the following combinations of: i) a forward scattered light intensity and a forward scattered light pulse width; ii) a forward scattered light intensity and a fluorescent light intensity; and iii) a forward scattered light pulse width and a fluorescent light intensity (see claim 13). This meets the limitation of claim 19. The reference further discloses that where a urine sample is examined, a dye capable of staining bacteria under an acidic state is preferably used (see paragraph [0020, lines 50-51). This meets the limitation of claim 16. Furthermore, the reference discloses that the working a dye on a sample may be carried out by mixing the sample, one by one or simultaneously, an aqueous solution containing the cationic surfactant and a solution containing the dye. However, where the dye to be utilized is unstable in the aqueous solution, it may be dissolved in a water-soluble organic solvent...solution containing the substance capable of reducing nitrite ions and/or the cationic surfactant. This improves storage stability of the dye (see paragraph [0028]). This reads on claim 1.

11. It is noted that the September 26, 2001, publication date of the Inoue patent is after Applicant's foreign priority date of November 1, 2000. However, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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Allowable Subject Matter

12. Sulfamic acid in combination of compound formula 10 (Dye A), quaternary ammonium salt and acidic buffer appears to be free of prior art.

Conclusion

13. Sulfamic acid in combination of compound formula 10 (Dye A), quaternary ammonium salt and acidic buffer appears to be free of prior art. Claims 1-19 are rejected. No claims are allowed.

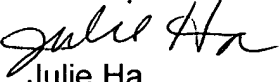
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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